(SPIC), Third World Network and Pharmaxil to discuss the proposed definition on counterfeit medicines. Discussions were held on each and every word of the definition of counterfeit medicine as it would affect the Indian Generic Industry which caters to the poor patient of India and other developing countries. Government is making efforts at every international forum to protect the interest of poor patients of the developing countries.

Eradication of polio

646. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that 5 polio cases have been reported from the State of Andhra Pradesh in 2007;

(b) if so, the details of type of polio cases reported;

(c) whether any case of polio was reported in the year 2008 from Andhra Pradesh;

(d) if so, the details thereof;

(e) whether it is also a fact that 900 cases of polio have been reported in 2007 in the country;

(f) if so, the details thereof; State-wise;

(g) the number of polio cases reported in 2008; State-wise;

(h) whether there is any plan before the Government to review polio eradication programme;

(i) if so, the details thereof; and

(j) if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) Yes, Sir.

(b) The 5 cases reported in 2007 from Andhra Pradesh are Wild Polio Virus Type 1.

(c) and (d) Yes Sir. The case reported in 2008 was Wild Polio Virus Type 3 & from East Godavari District.

(e) and (f) Yes, Sir. 874 Cases of Wild Polio Virus cases were reported during 2007. State wise, number of cases is given in the Statement-I (*See* below).

(g) The number of polio cases reported State-wise during 2008 is given in Statement-II (*See* below).

(h) to (j) The epidemiological situation of polio is reviewed by India Expert Advisory Group on polio (IEAG). The IEAG consists of International & National experts in the field of Public Health, Microbiologists, Pediatricians. The IEAG review the epidemiological situation of polio twice a year (Nov-Dec & May-June)

The last review was held on 10-11th Nov, 2008.

Statement-I

Statewise number of cases of Wild Polio Virus

State/UTs	2007
1	2
Uttar Pradesh	341
Bihar	503
Delhi	2
Haryana	6
Rajasthan	3
Maharashtra	2
West Bengal	2
Punjab	1
Orissa	1
Uttarakhand	6
Andhra Pradesh	5
Madhya Pradesh	0
Assam	0
Gujarat	1
Karnataka	1
Jharkhand	0
Chandigarh	0
Himachal Pradesh	0
Jammu & Kashmir	0
Tamil Nadu	0
Chhattisgarh	0
Kerala	0
Daman & Diu	0
D & N Haveli	0
Goa	0
Pondicherry	0
Andaman & Nicobar	0
Arunachal Pradesh	0
Lakshadweep	0

1	2
Manipur	0
Meghalaya	0
Mizoram	0
Nagaland	0
Sikkim	0
Tripura	0
TOTAL	874

Statement-II

Date as on 13th Feb, 2009

Number of Polio cases by state, 1999-2009

State/UTs	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
1	2	3	4	5	6	7	8	9	10	11	12
Uttar Pradesh	757	178	216	1242	88	82	29	548	341	305	5
Bihar	115	49	27	121	18	39	30	61	503	233	4
Delhi	73	3	3	24	3	2	1	7	2	5	1
Haryana	19	4	5	37	3	2	1	19	6	2	
Rajasthan	18	0	0	41	4	0	0	1	3	2	
Maharashtra	18	7	4	6	3	3	0	5	2	2	
West Bengal	21	8	1	49	28	2	0	1	2	2	
Punjab	4	0	5	2	1	0	1	8	1	2	
Orissa	0	0	0	4	2	0	0	0	1	2	
Uttarakhand	16	1	3	14	0	1	1	13	6	1	
Andhra Pradesh	21	0	0	0	21	1	0	0	5	1	
Madhya Pradesh	14	2	0	21	11	0	0	3	0	1	
Assam	0	0	1	0	1	0	0	2	0	1	
Gujarat	9	2	1	24	3	0	1	4	1		
Karnataka	21	8	0	36	1	0	0	1			
Jharkhand	8	1	2	12	1	0	2	1	0		
Chandigarh	2	1	0	1	0	0	0	1	0		
Himachal Pradesh	0	0	0	0	0	0	0	1	0		
Jammu & Kashmir	0	0	0	1	0	0	0	1	0		
Tamil Nadu	7	0	0	0	2	1	0	0	0		
Chhattisgarh	3	0	0	1	0	0	0	0	0		

1	2	3	4	5	6	7	8	9	10	11	12
Kerala	0	1	0	0	0	0	0	0	0		
Daman & Diu	0	0	0	0	0	0	0	0	0		
D & N Haveli	0	0	0	0	0	0	0	0	0		
Goa	0	0	0	0	0	0	0	0	0		
Pondicherry	0	0	0	0	0	0	0	0	0		
Andaman & Nicobar	0	0	0	0	0	0	0	0	0		
Arunachal Pradesh	0	0	0	0	0	0	0	0	0		
Lakshadweep	0	0	0	0	0	0	0	0	0		
Manipur	0	0	0	0	0	0	0	0	0		
Meghalaya	0	0	0	0	0	0	0	0	0		
Mizoram	0	0	0	0	0	0	0	0	0		
Nagaland	0	0	0	0	0	0	0	0	0		
Sikkim	0	0	0	0	0	0	0	0	0		
Tripura	0	0	0	0	0	0	0	0	0		
TOTAL	1126	265	268	1600	225	134	66	676	874	559	10

Compensation to victims of clinical trials

647. SHRI M.V. MYSURA REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether in view of growing number of clinical researches in the country and also in view of India becoming popular destination for clinical research, Government plans to formulate guidelines or code on clinical research with emphasis on giving compensation to participants who suffer economical, social, psychological and physical damages; and

(b) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Guidelines and requirements for conducting clinical trial in the country are specified in the Schedule Y of Drugs and Cosmetic Rules.

Clinical Trial in country is required to be conducted as per Schedule Y, which also mandates conformance to Indian Good Clinical Practices (GCP) Guidelines. The Para 2.4.7 of Indian GCP guidelines prescribes provision for compensation to trial subject by sponsor in case of any harm caused to them during the trials.

In order to ensure that Clinical trials are conducted in the country as per regulation & Good Clinical Practice (GCP) guidelines, it has been felt necessary to register the Organizations conducting clinical trial. Draft guidelines for the same have been prepared, which would be placed before forthcoming Drugs Technical Advisory Board Meeting to be held on 23.02.2009.